Framework for the assessment of uncommissioned third-party evidence

How the FSA uses evidence

The FSA prides itself in the transparent use of science and evidence to inform its advice and recommendations. Evidence enters the FSA from a variety of sources, and through all the Department's different functions. For example, the FSA conducts and funds its own research to keep abreast of changes in the food system and identify emerging issues; whilst industry and members of the public can submit evidence and views during public consultations. When new advice on food safety is required for Government, business or consumers, the Risk Analysis Process will be used to assess that risk and advise on its handling.

Our use and interpretation of scientific evidence and analysis is informed by the input, scrutiny and challenge of independent experts, for instance through the FSA's Scientific Advisory Committees (SACs).

Uncommissioned evidence

Sometimes evidence may be sent to the FSA by a member of the public, industry representative or consumer group outside of the usual research and consultation processes. Such uncommissioned evidence might be sent with a variety of aims such as filling a perceived gap in knowledge or suggesting a change relevant to a policy or legislation.

When the FSA receives such evidence, it will:

- be transparent about how such evidence is assessed and used to develop its evidence base, policy making and risk communication.
- assess evidence in its proper context using the principles of quality, trust and robustness.
- seek to minimise bias in its assessments of evidence by using professional protocols, its SACs, peer review and/or multi-disciplinary teams
- be open and transparent about the conclusions it has reached about any evidence submitted to it.

Guidelines

These guidelines outline the FSA's expectations concerning the standard of uncommissioned evidence that it receives, and provide guidance on how the strengths and weaknesses of this evidence will be assessed. They should therefore be used as a guide for anyone submitting evidence to the FSA – both those directly performing studies, and those choosing existing evidence to support their position.

The guidelines are not exhaustive as the work that the FSA undertakes covers a broad range of disciplines and areas of interest. Links to some of the organisations that provide detailed guidance for specific areas and disciplines is provided in the Helpful Links section at the end of this document.

The decisions that the FSA make on food safety are based upon a broad body of evidence. When the FSA receives new evidence on an existing issue in food safety it will consider it in the context of the body of evidence that has already been used to

inform a policy or decision. This will inform the assessment of whether any changes to the existing position may be needed.

In new, emerging or rapidly developing areas, a decision may need to be taken based upon limited evidence. The FSA will use the best available evidence to make this decision, recognise where there are gaps or limitations in knowledge, and be open to change as new evidence becomes available.

The guidelines are organised by the principles of quality, trust and robustness, as outlined below.

Quality

Evidence should be reliable and relevant to the question at hand. Clearly defining the context of the original study and the question originally asked can help to identify if the evidence is relevant. Using well-recognised methods and data analysis can help to ensure it is both relevant and reliable. If a novel method is used, a clear explanation of why it has been used and what advantage it brings is important. Data and analysis should be clearly presented, with a narrative that directly links them to the conclusions within the study.

Clarity

- All evidence sent to the FSA should be clearly laid out, outlining the study approach, the data collected, and analysis performed.
- If evidence has been collated from several sources this should be clearly indicated, and the method used for its collation and integration described.
- Precise language should be used to describe the aims of the study or research question relating this to the study design and conclusions.
- Methods should be described in enough detail that they could be independently reproduced – including the controls, reference standards and quality assurance measures used. This includes both study methods and methods for data analysis.
- A clear statement should be provided describing how data[1] were cleaned[2], processed and analysed, and why such approaches were taken.
- The conclusions of a study must be based on the evidence presented, with a clear narrative linking the data and analysis to those conclusions.

Relevance

- To assess the relevance of a study to a particular issue, the FSA will look at the context of the original study and the question(s) it was designed to answer. As key information about the way the study was conducted will be used to assess this, the clarity and transparency of the evidence are therefore important.
- The study design and the methods used should be justified with reference to the original question or hypothesis – including how potentially confounding variables were controlled for.

[1] We define data as all direct outputs from a study, including both quantitative and qualitative results, and digital images used to support analysis and conclusions.
[2] Where data cleaning refers to the detection and removal of incorrect or corrupt data points, duplicates or empty fields, and ensuring consistency of units and formatting.

- Consider the relevance of the study population, specimen or substance to the target population, specimen or substance. This is particularly important when considering the biological relevance of a study and its conclusions.[3]
- If the study is qualitative, a comprehensive description of the context of the work should be included. For example, the culture, livelihood, community, socio-economic status and environment of participants.
- Statistical analysis is essential in scientific studies. Studies should include a clear outline of the methods used, and why they were chosen, with an explanation of what question the analysis aimed to answer. Statistical point estimates and confidence intervals are recommended alongside significance testing.
- Where the evidence relates to a new method, outline the context in which the method should be used and why. Where relevant, make clear the advantages and drawbacks relative to more established methods.

Reliability

- Where possible, methods recommended by national and international bodies such as the FAO, OECD and the Codex Alimentarius Commission, or methods widely used in academic literature should be used.
- Good governance should be practiced when performing research. Refer to best practice guidelines such as the OECD's Principles of Good Laboratory Practice.
- Whether routine or not, all methods used should be referenced. If a standard method has been adapted, the study should state why and describe the differences. If a new method is proposed, a description of how it differs from the standard method(s), and where possible a comparative study should be provided.
- All evidence must include consideration of uncertainty[4]. Where possible this should be quantified using recognised methods. If the uncertainty is associated with an expert judgement, state whether it is qualitative or quantitative, and how it was discerned.
- Variability must also be considered, and where possible quantified[5]. Where variability has been controlled for in a study, consider if this affects generalisability to the target population, specimen, or substance.
- If mathematical models are used, the results of the sensitivity analysis performed should be provided, stating which parameters were tested, which were not and why.

[3] The work on Biological Relevance and Statistical Significance led by the Committees on Toxicity, Carcinogenicity and Mutagenicity will explore this in further detail.
[4] We use the definition of uncertainty provided by the Committee on Toxicity: as *the estimated sum of the limits in knowledge*. We include limitations to apparatus, experimental techniques, models and study designs, as well as essential unpredictability.
[5] Variability is defined as the inherent heterogeneity between individuals or groups, or over time or space. This may be humans, animals or other specimens.

Trust

Transparency and impartiality are key in providing confidence that evidence is trustworthy. Evidence that is shared transparently will include access to all underlying data, a clear explanation of the methods used and why, and the limits to the evidence. This includes stating uncertainties, variability and assumptions, indicating where results differ from comparable investigations and where there is dissenting opinion among experts. Any evidence and its assessment is at risk of bias, but this can be mitigated by ensuring that sources of bias are recognised, peer review is performed and challenge is built into the assessment process.

Transparency

- Openness and transparency are core principles of the way the FSA works; evidence submitted to the FSA should also demonstrate these principles as far as reasonably possible.
- In addition to clearly presenting all relevant data and associated analysis, access to the raw and omitted data from the study should be provided. If this is not possible, state why.
- Known gaps in the evidence should be stated and limitations to models or study designs outlined. This includes assumptions on what is or is not important for the question being asked, and therefore what has been included or excluded from the study or model design.
- Consider alternative hypotheses and make comparisons to the published body of research on the area, stating where results differ or where there is disagreement in expert opinion.
- Clearly indicate when evidence is compiled from a range of sources. Reference all sources and state the method used to compile the evidence, for example, using widely accepted guidelines for evidence synthesis such as meta-analysis and systematic review procedures.

Impartiality and bias

- Increased risk of bias reduces the confidence in the outputs of a piece of evidence.
- All potential sources of bias should be clearly described, considering each stage of the study and any actions taken to mitigate them should be stated. The sources of bias and appropriate mitigating actions will be dependent upon on the type of study being performed.
- Where data are omitted from a study report, this should be clearly stated, with reasoning. This includes both full data sets and individual data points. If evidence is from a range of sources, the way in which sources were chosen or omitted should be given.
- Where expert judgement is used, state why, how the experts were chosen and the initial question that was asked of them. Any underlying data or evidence that the judgement is based upon should be provided, and a statement of uncertainty should be included with the judgement.
- If the evidence used is not published in a peer-reviewed journal, any critical review that has been performed should be described.
- In all instances, sources of funding and conflicts of interest must be stated.

Robustness

For evidence to be robust, a broad body of evidence should be considered from several perspectives, with each piece of evidence weighed based on its quality and trustworthiness. The body of evidence will be made more robust if the pieces of evidence are reproducible using the same and different methods. If an outcome is consistently observed when tested using different methods and populations, this provides confidence that the outcome itself is robust.

Consistency

- The FSA expects that studies submitted to them should be reproducible. To demonstrate reproducibility, describe how tests were replicated and the extent of any variation in the observed results.
- The clarity and transparency of a study, as well as the use of standard methods, reference standards and quality control methods can help ensure that a study can be repeated by other researchers.
- If several independent studies are performed repeating the same or similar tests and gaining the same or similar outcomes, this will increase confidence in the outcome.
- The robustness of an outcome can be tested by varying parameters within the study, and by using different methods to test the same relationship or outcome (triangulation). This may be done in a single study, or by comparing the outcomes of several studies.

Adequacy

- Explain the importance of the evidence with reference to the broader body of evidence to which it contributes. Consider whether evidence highlights any gaps in the existing body of evidence, and how much it increases the understanding of a new or emerging area.
- Different types of evidence may need to be combined for a comprehensive assessment of an issue to be undertaken[6]. Consider the other types of evidence that are required when assessing an issue and explain how your evidence relates to them.
- The adequacy of a piece of evidence will vary depending on the type of study and the question being asked. However, criteria such as the magnitude of any effect, the power of a study, and its applicability to the target population, specimen or substance may be considered.
- Significance testing is often used to indicate the magnitude of a result, but it is not by itself sufficient to indicate that a piece of evidence is strong or will translate to an important real-world impact. Consider the relevance of the study and the statistical test to the decision or policy that the evidence is being used to address[7].

[6] For instance, as described in the Committees on Toxicity and Carcinogenicity's guidelines on the synthesis and integration of epidemiological and toxicological evidence.
[7] The work on Biological Relevance and Statistical Significance led by the Committees on Toxicity, Carcinogenicity and Mutagenicity will provide further detail of how this is assessed by SACs.

Helpful links

Organisation/group/ body	Area	Description
FSA COT ACMSF ACNFP ACSS ACAF	Science Advisory Committee guidance for evidence assessment	Guidance from the SACs is published on their pages, including guidance on how evidence should be assessed and integrated
FSA Regulated product authorisation	Guidance for evidence submission	Guidance on what is required when providing evidence for approval, for instance for a regulated product
EFSA	Guidelines and opinion	European Food Safety Authority Journal – through which all guidelines and opinion are published
EQUATOR network	Reporting of health research	Library of reporting guidelines for the most commonly used study types in health research.
OECD Good Laboratory Practice Good in vitro method practices	Guidance on methods and governance in laboratory practice	Principles and technical guidance for laboratory practice used for regulatory practice, including the Mutual Acceptance of Data.
Food and Agriculture Organization of the United Nations (FAO)	Guidance and methods for risk analysis	Technical guidance for methods to be used during risk assessment for food safety.
Codex Alimentarius Commission	Guidance and standards for risk analysis and the maintenance of food safety standards	Codex standards include guidelines and recommendations for assessing and implementing food safety.
UK Accreditation Service	Accreditation body	Accredits organisations providing laboratory testing services for regulatory purposes, including the methods used.
International Organization for Standardization and European Committee for Standardization	Standards for testing in food safety	ISO and CEN develop international standards for testing in food safety.
International Programme on Chemical Safety	Guidance for risk assessment	A toolkit for the assessment of risk from exposure to chemicals
UK Statistics Authority	Code of Practice for Statistics	Code of practice for the production and release of official statistics, that can be voluntarily applied by any organisation
NICE	Guidance for assessing evidence	Detailed guidelines for weighing evidence in a health and social care context